

CLIPS **BnC** BIO&CRO



The best New drug development
through Globalized Top-tier CRO



www.clipsbnc.com

About CLIPS BnC New drug development

CLIPS BnC new drug development is a biopharmaceutical company devoting itself to the discovery of global innovative drugs with unmet needs.

Using our deep business experience in clinical trial services for biological clients and technology commercialization consulting, we are striving to develop a wide range of R&D pipelines, including limbal stem cells(LSCD101) for treatment of rare diseases and first-in-class candidates(cancer immunotherapy, RSV vaccine, and MRSA vaccine) via scientific networks with extinguished professionals.

In addition, CLIPS BnC is new drug development company armed with R&D insight and capacity, we are also engaging in new drug development by efficiently dealing with the technology commercialization process to select and evaluate the project, via a partnership with global technology consulting groups having extensive new drug R&D experience and expertise, as well as our carefully tailored consultation on licensing-out activities.



CLIPS BnC History of New drug development

2014 ~ 2015

- Founded CLiPS Co., Ltd.
- Became a full member of the Korea Biomedicine Industry Association
- Signed an MOU with the Clinical Trials Center at Seoul National University Hospital

2016 ~ 2017

- Signed an MOU with the Vaccine Bio Research Institute at the Catholic University of Korea
- Signed a technology transfer agreement for the treatment of limbal stem cell (LSC) deficiency with the Catholic University of Korea
- Signed an MOU with global law firm Epstein Becker & Green, USA
- Signed an MOU with the Biomedical Research Institute at Inha University Hospital
- MFDS licensed research institute

2018

- Signed an MOU with Beijing Supertrack Pharma-Tech, China
- Vector System BCG technology transferred from the R&BD Foundation at Seoul National University Obtained certification as a venture company

2019 ~ 2020

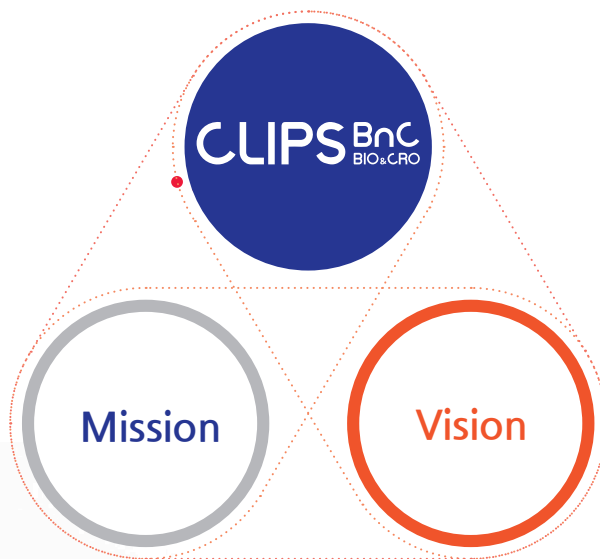
- Obtained approval for clinical phase 1 of limbal stem cell (LSC) treatment
- Obtained approval for the establishment of an R&D service from the Ministry of Science and Technology
- Project confirmed for 2019 Ministry of Trade, Industry and Energy R&BD (Technology development for commercialization of limbal stem cell for treatment of refractory limbal stem cell deficiency)
- Applied for a staphylococcus vaccine patent
- Founded Qingdao Hanchuang Biomedical Technology Co., Ltd. (Joint venture company) with Beijing Science and Technology Development Co., Ltd. in Qingdao, China
- Introduced Yonsei University's RSV vaccine technology

2021 ~ Current

- Obtained approval for clinical phase II of Limbal Stem Cell (LSC) treatment.



Our Mission & Vision



Mission

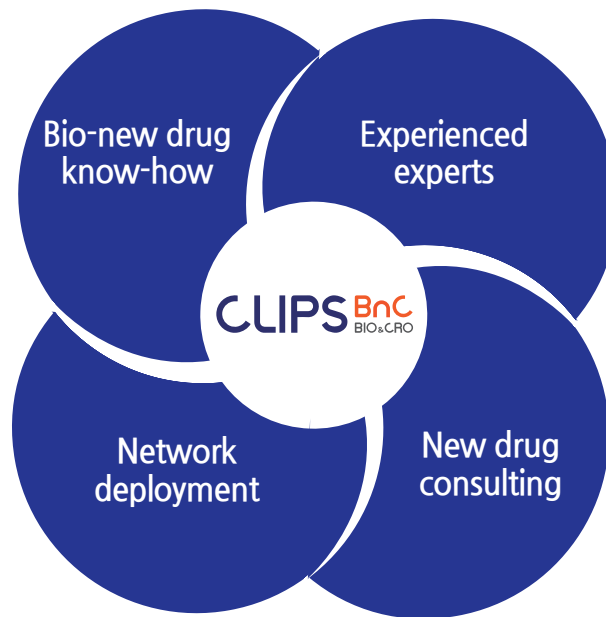
Aim for Health Care Group with Best Value

Vision

“The company that provides total solution for Health Care with based on Customer”



New drug development business



Extensive clinical trial services

- Unrivaled clinical experience and outcome for new biopharmaceuticals and cell therapies
- Extensive clinical know-hows in all areas of therapeutic expertise, which can be efficiently used in new drug development process.

Scientific network for new drug development

- Fostering of closer collaboration with R&D groups and novel patent developers/holders via longstanding cooperation
- Building the basis for acceleration of new drug development and joint development of patent commercialization

Top professionals in bioindustry

- Experienced experts with vast knowledge in a variety of biopharmaceutical formulation sectors
- Minimization of trials & errors in new drug development process and possible enhancement of clinical efficiency

New drug consulting

- Extensive consulting experience in new biopharmaceutical commercialization across all phase ranging from planning to market authorization, and production/marketing
- Actual outcome of technology commercialization and its related know-how

Research group

Professor Kang Jin-han Catholic University

- Clinical Director of Pediatrics and Head Professor of Pediatric Medicine at Seoul St. Mary's Hospital
- Director of the Institute of Biomedical Industry, Head of the Vaccine-Bio Research Institute
- Director at the Catholic Medical Center Research Office and Head of the Industry-Academia Cooperation Group of the Catholic University of Korea
- Director of the Korean Society of Pediatric Infectious Diseases, the Korean Society of Infectious Diseases, the Korean Pediatric Society, the Korean Vaccine Society, etc.

Professor Lee Bok-ryoul Pusan National University

- Professor at the Department of Pharmacy, College of Pharmacy
- Doctor at Osaka University, Japan
- Postdoc at Johns Hopkins University, U.S.A.
- Vice-Chairman of the Pharmaceutical Society of Korea
- Chief Director of the Korea Drug Development Fund
- Received the Handok Academic Research Award and Knowledge Creation Award

Professor Chung So-hyang Catholic University

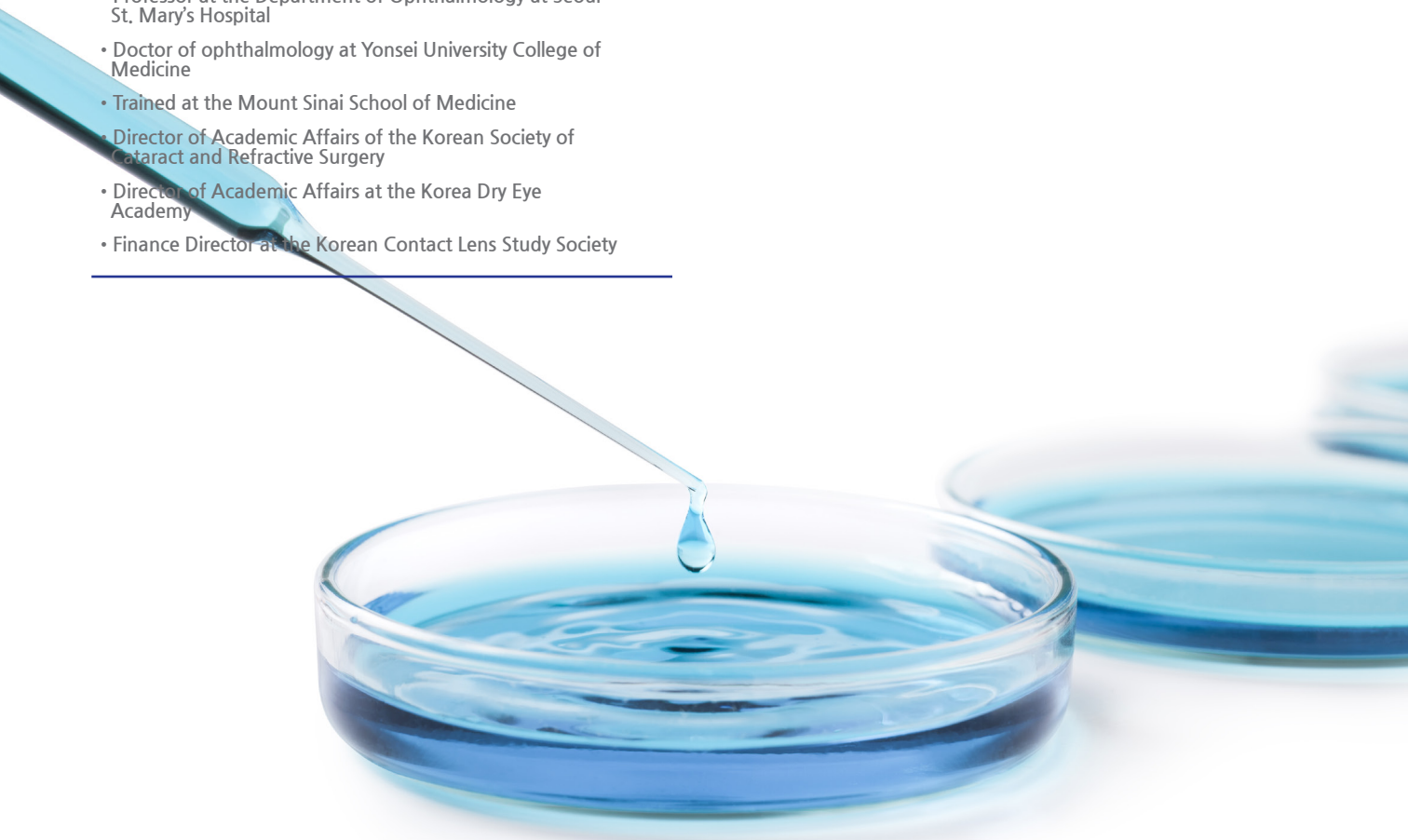
- Professor at the Department of Ophthalmology at Seoul St. Mary's Hospital
- Doctor of ophthalmology at Yonsei University College of Medicine
- Trained at the Mount Sinai School of Medicine
- Director of Academic Affairs of the Korean Society of Cataract and Refractive Surgery
- Director of Academic Affairs at the Korea Dry Eye Academy
- Finance Director at the Korean Contact Lens Study Society

Professor Kim Bum Jun Seoul National University

- Head Professor in the Department of Microbiology at Seoul National University College of Medicine
- Master and doctor at the Seoul National University College of Medicine
- Secretary of the Korean Society for Microbiology and the Korean Society of Virology
- General Secretary of the Federation of Korean Microbiological Societies
- Awarded an Academia Prize for Young Basic Medical Scientists by the Korea Institute of Medicine

Professor Choi Young-deuk Yonsei University

- Chief of the Department of Urology at Severance Hospital
- Chief of the Urologic Cancer Center at Yonsei Cancer Hospital
- Chief of the Medical Device Clinical Trials Division at Clinical Trials Center
- Head of the Robot Surgery Center
- Team Leader of the Urologic Cancer Clinic



Our Pipelines & Timeline



	Definition	Status
Limb stem cell therapy	Auto logus Stem cell based treatment for limbal stem cell deficiency, a rare eye disease caused by genetic and acquired damages, thus resulting in corneal opacity, perforation, and visual loss	Phase 2 IND Approved
	Allo geneic Stem cell based treatment for limbal stem cell deficiency, a rare eye disease, associated with genetic and acquired damages, resulting in corneal opacity, perforation, and visual loss	Nonclinical study complete
Cancer immunotherapy (BCG based)	An immunotherapy to treat bladder cancer and other tumors by using Mycobacterium that stimulates the immune response, including cytokines	<i>in vivo</i> (first in class)
Respiratory syncytial virus vaccine	A nanoparticle subunit vaccine to prevent Respiratory Syncytial Virus (RSV) that causes serious respiratory infection in pediatric and geriatric populations	<i>in vivo</i> (first in class)
<i>S. aureus</i> vaccine	A multi-valent subunit vaccine to prevent <i>S. aureus</i> -related skin wound, osteomyelitis, and myocarditis associated with inflammation in a variety of organs	<i>in vivo</i> (first in class)

Patent



Item	Patent No	Process	
Limb Stem Cell Treatment	10-1645901 US,EU,JP,CN	Phase 2 IND Approval	
pMyong2 Vector (shuttle vector)	Enhanced BCG	Patent yet to register, tech completion	
	Cancer immunotherapy	KR 10-1291668 US 8,841,432 KR 10-2079761	Secured recombinant <i>M.smegmatis</i>
	HIV-1 Vaccine		Secured recombinant <i>M.smegmatis</i>
RSV vaccine	KR 10-2019-0171057 (Aug, 2020, PCT)	Manufacturing Nanoparticle strain	
<i>S. aureus</i> vaccine	Human use	Selected 6 Ag and production strain	
	Animal use	KR 10-2019-0094450 (Sept, 2020, PCT)	Selected 6 Ag and production strain

Limbal Stem Cell Plate Technology for Treatment of Intractable Limbal Stem Cell Deficiency



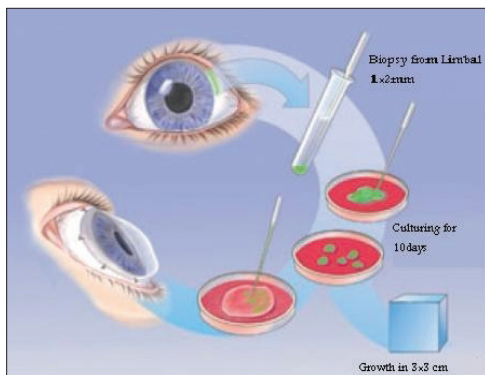
Definition

It is a disease caused by the lack of limbal stem cells capable of continuously regenerating corneal epithelium because extensive limbal damage occurs due to innate and acquired factors

Causes

LSCD is a rare, progressive, ultimately blinding corneal disease of wide-ranging etiology found throughout the world.

It has been associated with genetic disorders, such as aniridia, Peter's Anomaly and KID syndrome. The acquired causes are inflammatory insults, infections, chemical or thermal burns of eye, ocular surgeries or cryotherapies etc.



Limbus-derived epithelial cell transplantation treatment

For limbal stem cell deficiency has a principle that the biopsy limbal tissue is cultured **by in vitro transplantation to make a cell plate that amplifies limbal stem cells, and then the stem cells are supplied by implanting them on the eyeball surface of the patient.**

Development Status

- Establishment and production of limbus-derived epithelial cell plate manufacturing process in GMP facility
- Application for MFDS phase II clinical trial
→ **In June 2021 it was IND approved.**
→ Technology transfer to CMO is currently in progress.

Domestic and International Competing Products

- As far as stem cell therapy has been approved, the only product that can be used for ophthalmologic diseases such corneal limbal deficiency is Holoclar of the Chiesi company in Italy, and the European Commission has conditionally allowed the introduction of the EU countries.
→ **100,000 Euros (approximately 130 million won) estimated**
- Excellent economic feasibility with differentiated manufacturing process/quality control → **High competitiveness**

Domestic & International Applications and Registration Status

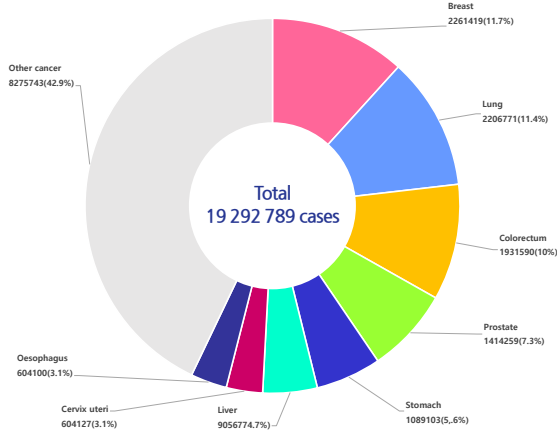
Classify	Patent name	Number	Date
Domestic Registration		10-1645901	Jun, 2016
International Application		PCT/KR2016/008003	Jul, 2016
US Application	Limbal stem cell cultivation method using amnion slide supporter	16/066.389	Jun, 2018
Europe Application		16881915.9	Jul, 2018
Japan Application		2018.553030	Jun, 2018
China Application		20160076831.4	Jun, 2018

Recombinant *Mycobacterium smegmatis* as an anticancer immunotherapy

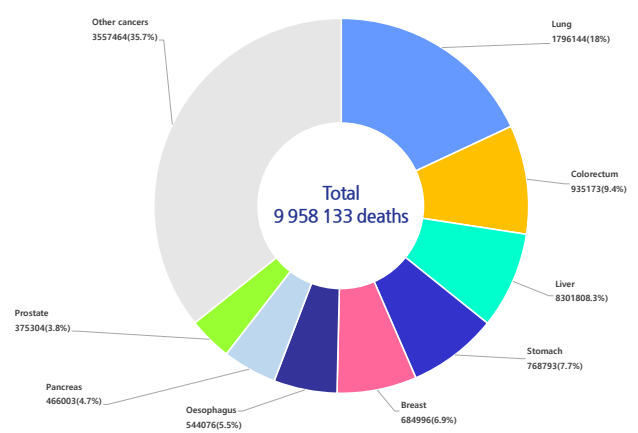


Cancer statistics in 2020

Number of new cases in 2020, both sexes, all ages



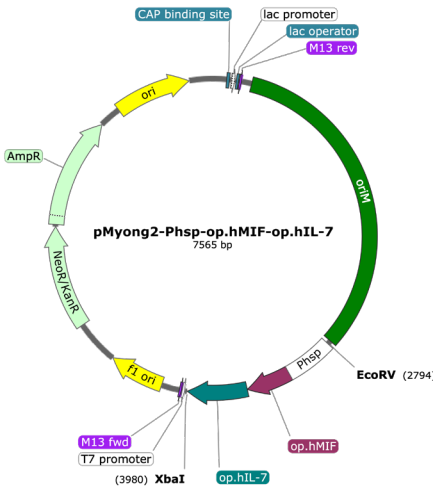
Number of deaths in 2020, both sexes, all ages



- Lung, colorectal cancers(CRS) and Liver account for 36% of all death cases, with lung cancer alone accounting for 18%
- Breast cancer, lung cancer, and CRC account for 33% of all new diagnoses, with breast cancer alone accounting for almost 11.7%

Source : Globocan 2020, International agency for Research on Cancer

Target construct



IL-7

- T cell development and maintain and restoring homeostasis of mature T cells
- 154 aa, 17.7kD
- Important in Naive T cell and memory T cell development, TCR diversity
- A lot of Clinical trials using IL-7 against various solid tumors

MIF

- Macrophage Migration Inhibitory Factor, - homotrimeric molecule
- 115 aa, 12.5kD
- Important regulator of innate immunity
- Acting as a tumor antigen

Relative Patents

Shuttle vectors for *Mycobacteria-Escherichia coli* and uses thereof. Korea and USA (Patent No., 10-1291668 and US 8,841,432 B2)

특허번호 10-1291668

(13) 대한민국특허청(KR) (45) 공고일자 2021년09월01일
(12) 등록특허공보(B1) (46) 등록일자 2021년09월01일

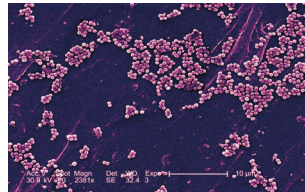
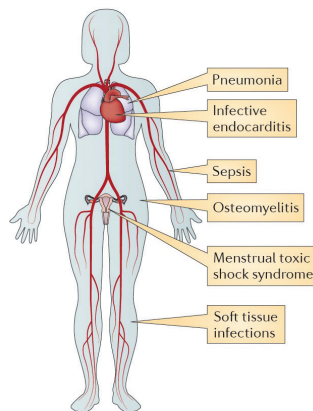
(51) 국제특허분류(Int. Cl.) C12N 25/00 (2006.01)
C12N 25/09 (2006.01) C12P 22/00 (2006.01)
(52) 출원번호 10-2018-000587
(53) 출원일자 2018년08월20일
(54) 공개일자 2021년09월01일
(55) 국제공개번호 WO/2019/13373 A1
(56) 선행특허: KR2018-0111111, KR2018-0111112, KR2018-0111113, KR2018-0111114, KR2018-0111115, KR2018-0111116, KR2018-0111117, KR2018-0111118, KR2018-0111119, KR2018-0111120, KR2018-0111121, KR2018-0111122, KR2018-0111123, KR2018-0111124, KR2018-0111125, KR2018-0111126, KR2018-0111127, KR2018-0111128, KR2018-0111129, KR2018-0111130, KR2018-0111131, KR2018-0111132, KR2018-0111133, KR2018-0111134, KR2018-0111135, KR2018-0111136, KR2018-0111137, KR2018-0111138, KR2018-0111139, KR2018-0111140, KR2018-0111141, KR2018-0111142, KR2018-0111143, KR2018-0111144, KR2018-0111145, KR2018-0111146, KR2018-0111147, KR2018-0111148, KR2018-0111149, KR2018-0111150, KR2018-0111151, KR2018-0111152, KR2018-0111153, KR2018-0111154, KR2018-0111155, KR2018-0111156, KR2018-0111157, KR2018-0111158, KR2018-0111159, KR2018-0111160, KR2018-0111161, KR2018-0111162, KR2018-0111163, KR2018-0111164, KR2018-0111165, KR2018-0111166, KR2018-0111167, KR2018-0111168, KR2018-0111169, KR2018-0111170, KR2018-0111171, 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Staphylococcus aureus Vaccine

Staphylococcus aureus

S.aureus causes **life-threatening diseases**, including pneumonia, infective endocarditis, toxic shock syndrome and sepsis, as well as minor diseases such as soft tissue infections.

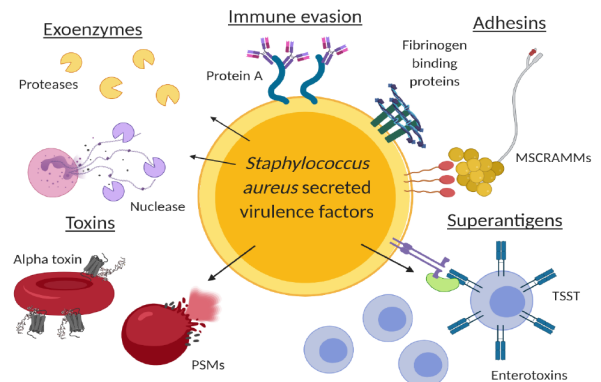


Target Population

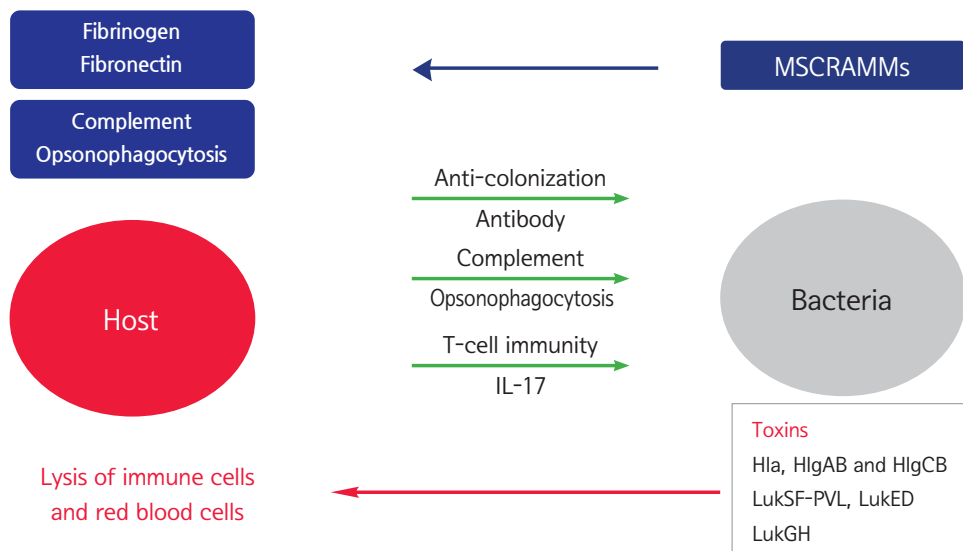
- Dialysis
- Chronic Diseases
- High-risk Surgery
- Diabetes
- Elderly at high-risk
- hospitalization

Various virulence factors in *S. aureus*

Staphylococcus aureus is a dangerous and versatile pathogen that can cause a multitude of different diseases. It has defined by a large repertoire of virulence factors.



Immune system vs. *Staphylococcus aureus*



The Multivalent Subunit Vaccine

- 2 Antigens from MSCRAMMs to block the colonization & immune evasion system
- 4 Antigens from Toxins to block the lysis of immune cells

Patent

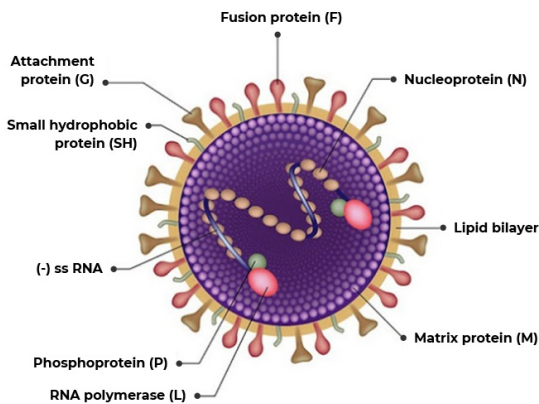
Classify	Patent name	Number	Date
Domestic application	A novel composition for preventing or treating <i>Staphylococcus aureus</i> infections diseases	10-2020-0114435	2020.09.08



Respiratory Syncytial Virus Vaccine

Respiratory Syncytial Virus & Pre F- protein

RSV infection causes bronchitis and pneumonia in infants, the elderly, and immunocompromised patients, and is a great threat to neonatal rooms and postpartum care centers, since they are easily transmitted by contact and respiratory droplets.



Respiratory Syncytial Virus Infection

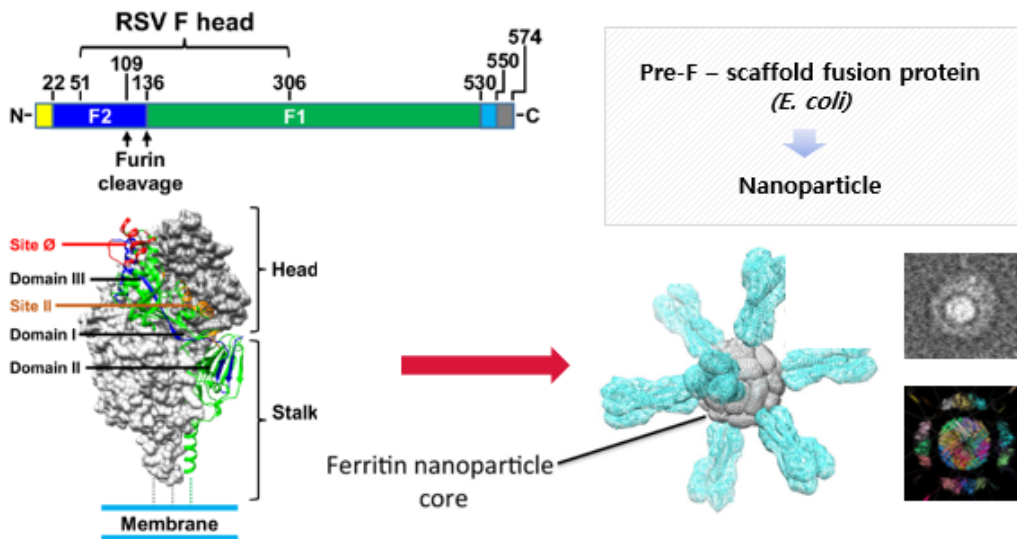
- 2.1 million** Pedaiatric Outpatient visits annually in the US
- 200,000** Infant deaths globally per year
- 2-3%** Of all infants < age 2 are hospitalised with RSV
- 14,000** Deaths in people > 65 years in the US every year
- 175,000** hospitalisations due to RSV in the early annually in the US
- 2 million** Consultation with physicians in the US every year due to RSV infection
- 80%** RSV is the leading cause of severe infection in severely immunocompromised patients, with mortality rates as high as

"RSV infection in children, the immunocompromised and the elderly causes serious disease and there is a significant unmet medical need for treatment,"

John DeVincenzo, MD, Professor of Pediatrics and Professor of Microbiology, Immunology, and Biochemistry, University of Tennessee School of Medicine

Nanoparticle RSV Vaccine

We develop Nanoparticle RSV vaccine based on the fusion of Stable pre-F protein and scaffold protein produced in *E. coli*.



Patent

Classify	Patent name	Number	Date
Domestic application	A Method for enhancing soluble expression of target proteins by using fusion protein of WHEP domain	10-2019-0171057	2019.12.19



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